REMARKS

Entry of the Amendment, reexamination, and further and favorable reconsideration of the subject application in light of the following remarks, pursuant to and consistent with 37 C.F.R. §§ 1.114 and 1.111, are thus respectfully requested. Applicants have submitted the Amendment / Response filed on September 1, 2010 anew, but now including a request for an Examiner's Interview.

1. Request for Examiner Interview

Applicants submit Form PTOL413A requesting an in-person interview with the Examiner to discuss the claim amendments and arguments to advance prosecution. Applicants request that the Examiner contact the undersigned attorney to schedule an interview prior to responding to the merits of this response.

2. Status of the Claims

The status of the claims following entry of the amendments is as follows:

Claims canceled: 2-3, 6-7, 14-15, 17-20, and 24-30

Claims pending: 1, 4-5, 8-13, 16, and 21-23

Claims withdrawn: None

Claims rejected: 1, 4-5, 8-13, 16-18, 21-23, and 26-30

Claims objected: None

Claims allowed: None

3. Support for the Amendments

Applicants amend claim 1 to more precisely recite the claimed subject matter. Support for the amendments of claim 1 can be found at least from (1) the original claims 1 and 18-20, and (2) the last paragraph on page 18 and the first paragraph on page 19 of the Specification.[1]

[1] "When the first compound contains other compounds, or when it can separate fatty acids other than LCPUFA, the proportion of LCPUFA in all suppliable fatty acids from the total amount of the first component should be not less than 25 percent by weight, preferably not less than 33 percent by weight, or more preferably not less than 50 percent by weight."

Applicants do not believe that any prohibited new matter is being introduced by the entry of the above amendments.

The claims have been amended without prejudice to, or disclaimer of, the canceled subject matter. Applicants reserve the right to file a continuation or divisional application on any subject matter canceled by way of amendment.

4. Acknowledgement of Information Disclosure Statements

Applicants appreciate the Office's acknowledgement of the Information Disclosure Statements (IDSs) filed December 9, 2009 (resubmitted April 2, 2010) and March 22, 2010.

5. Withdrawn Rejections

Applicants appreciate the withdrawal of the following rejections:

1) the rejection of claims 1-5 and 8-23 under 35 U.S.C. § 112, first paragraph (Written Description);

2) the rejection of claims 14-20 under 35 U.S.C. § 112, first paragraph (Written Description);

3) the rejection of claims 1-2, 4-5, and 8-23 under 35 U.S.C. § 112, second paragraph (Indefiniteness);

4) the rejection of claims 14-18 under 35 U.S.C. § 112, second paragraph (Indefiniteness);

5) the rejection of claims 2-3 and 18-20 under 35 U.S.C. § 112, second paragraph (Indefiniteness);

6) the rejection of claims 2-3 and 17-20 under 35 U.S.C. § 112, second paragraph (Indefiniteness);

"As noted above, the LCPUFA in the present invention is preferably arachidonic acid (AA) and/or docosahexaenoic acid (DHA). In this case, the proportion of arachidonic acid (AA) in all suppliable fatty acids from the total amount of the first component should be not less than 1 percent by weight, preferably ***not less than 20.5 percent by weight***, more preferably not less than 23 percent by weight, and even more preferably not less than 40 percent by weight. Further, the proportion of docosahexaenoic acid (DHA) in all suppliable fatty acids from the total amount of the first component should be not less than 11 percent by weight, preferably ***not less than 22.5 percent by weight***, more preferably not less than 40 percent by weight, and even more preferably not less than 45 percent by weight." (emphasis added).

7) the rejection of claims 14-20 under 35 U.S.C. § 112, second paragraph (Indefiniteness);

8) the rejection of claims 1-5, 8-17, 19, 21, and 23 under 35 U.S.C. § 102(b) over **Ultimate Ginkgo** (*available at* http://www.edietstar.com/fact_sheet/ultimate_ginkgo.pdf, March 12, 2003 as of Internet Archive) ("Ultimate Ginkgo");

9) the rejection of claims 1-5 and 8-19 under 35 U.S.C. § 102(b) over **Hiratsuka** et al., U.S. Publish Patent Application No. 2003/0190392 A1; and

10) the rejection of claims 18, 20, and 22 under 35 U.S.C. § 103(a) over Ultimate Ginkgo in view of **Stordy**, U.S. Patent No. 6,150,411 and **Birch** et al., 42 DEV. MED. CHILD NEUROL. 14 (2000).

Office Action, page 2.

6. Rejection of the Claims Under 35 U.S.C. § 103(a)

6.1. Claims 1, 4-5, 8-13, 16-18, 21-22, 26-28, and 30

The Office newly rejects claims 1, 4-5, 8-13, 16-18, 21-22, 26-28, and 30 under 35 U.S.C. § 103(a) as allegedly unpatentable over **Ponroy**, U.S. Patent No. 5, 591,479 ("Ponroy"). Ponroy allegedly teaches a composition comprising phospholipids and fatty acids, wherein the composition can be used as a nutritional supplement for premature babies. Office Action, page 3. Ponroy's composition allegedly contains (1) arachidonic acid at a proportion of about 8.5% of the total fatty acid; (2) docosahexaenoic acid (DHA) at a proportion of about 9% of the total fatty acid; and (3) 1-20% of cerebral phospholipids. *Id.* The Office alleges that Ponroy's composition may contain glycerides as the source of the various fatty acids. *Id.* Ponroy's composition allegedly renders the claimed composition obvious. *Id.*

Applicants traverse the rejection to the extent it applies to the amended claims. "[O]bviousness requires a suggestion of ***all*** limitations in a claim." *CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1342, 68 U.S.P.Q.2d 1940, 1947 (Fed. Cir. 2003) (citing *In re Royka*, 490 F.2d 981, 985, 180 U.S.P.Q. 580, 583 (C.C.P.A. 1974) (emphasis added). Obviousness cannot be proven merely by showing that a known component or method could have been modified by routine experimentation. The Office must provide evidence that a skilled artisan would have had some ***apparent reason*** to modify a known component or method in a way that would result in

the claimed composition or method. *See e.g. Ex parte Whalen*, 89 U.S.P.Q.2d 1078, 1084 (Bd. Pat. App. & Int. 2008) (precedential).

Amended claim 1 recites, *inter alia*, that (1) a composition comprises "a LCPUFA supply compound as a first component"; (2) the LCPUFA supply compound contains "at one selected from the group consisting of: arachidonic acid and docosahexaenoic acid"; and (3) "the proportion of arachidonic acid in all fatty acids to be supplied from the total amount of the first component is no less than 20.5 percent by weight, and the proportion of docosahexaenoic acid in all fatty acids to be supplied from the total amount of the first component is no less than 22.5 percent by weight." Ponroy's composition contains (1) arachidonic acid at a proportion of about 8.5% of the total fatty acid, and (2) docosahexaenoic acid (DHA) at a proportion of about 9% of the total fatty acid. *See* Ponroy, col. 2, lines 41-52. Both the arachidonic acid and DHA proportions are outside the presently claimed ranges. There is no evidence that a skilled artisan would have had an ***apparent reason*** to adjust the arachidonic acid and DHA proportions of Ponroy's composition to the presently claimed ranges. Ponroy thus fails to teach at least the claimed arachidonic acid and DHA proportions. Without all claim elements taught, there can be no expectation of success to make or use the presently claimed composition predictably.

Additionally, the presently claimed compositions offer unexpected advantages. Applicants newly discovered the following:

> The inventors of the present invention diligently worked to solve the foregoing problems. In accomplishing the present invention, the inventors have found that ***a considerable amount of LCPUFA-PL can be produced in the body when an oil or fat composition provided as a mixture of phospholipids (do not necessarily contain LCPUFA-PL) and a LCPUFA supply compound (does not necessarily contain phospholipids) is ingested***. This was observed to be the result of highly efficient uptake of the LCPUFA supplied from the LCPUFA supply compound, which occurs when the non-LCPUFA-containing lysophospholipids produced by the hydrolysis of the phospholipids in the digestive system are reassembled in the small intestine cells. The inventors have also found that the LCPUFA-PL so produced was actually absorbed through the lymph vessels.

See Specification, the first full paragraph on page 8 (emphasis added). Accordingly, the presently claimed compositions "can efficiently increase the LCPUFA-PL level in the body by taking into account the metabolism in the body and without directly using LCPUFA-PL."

Paragraph bridging pages 7-8 of the Specification; *see also* Examples 1-6 spanning pages 42-52 of the Specification. Ponroy does not describe the above-listed advantages.

Instead, Ponroy's composition is "intended to compensate for essential fatty acid deficiencies in the food of delicate of malnutritioned patients," such as premature infants. *See, e.g.*, Ponroy, col. 1, lines 7-10. Thus, Ponroy's teaching is directed to a different purpose and provides no rationale to effectively increase the LCPUFA-PL level in the body. The above-described advantages of the presently claimed compositions are therefore unexpected.

In view of above arguments, amended claim 1 is nonobvious. Dependent claims 4-5, 8-13, 16, and 21-22 are likewise nonobvious. Claims 17-18, 26-28, and 30 are canceled, mooting the rejection. Accordingly, Applicants respectfully request withdrawal of the rejection and allowance of the claims.

6.2. Claims 1, 4-5, 8-13, 16-18, 21-23, and 26-30

The Office newly rejects claims 1, 4-5, 8-13, 16-18, 21-23 and 26-30 under 35 U.S.C. § 103(a) as allegedly unpatentable over Ponroy as applied to in Section 6.1. *supra*, and further in view of Ultimate Gingko. The Office admits that Ponroy does not teach a composition in the form of a tablet. Office Action, page 6. Ultimate Gingko is only relied upon for teaching a composition in the form of a tablet, wherein the composition comprises DHA, phosphatidyserine, other phospholipids, and excipients. *Id.* The DHA proportion of the Ultimate Gingko's composition is allegedly at least 23%. *Id.* The Office alleges that a skilled artisan would have been motivated to combine Ponroy and Ultimate Gingko to make the presently claimed composition. *Id.*

Applicants traverse. To establish *prima facie* obviousness using a combination of multiple references, the Office must show that the combination or modification must have expected and predictable results. *See* M.P.E.P. § 2143. In the present rejection, Ultimate Gingko does not cure the defects of Ponroy discussed in Section 6.1. *supra*. Ultimate Gingko's composition contains DHA in the form of a free fatty acid. The present claimed compositions, however, exclude free fatty acids from the first component. Amended claim 1 recites the first component as "a LCPUFA supply compound" that is "at least one kind selected from the group

consisting of fatty acid alcohol ester, triglyceride, diglyceride, monoglyceride, glycoglycerolipid, sphingolipid, sugar ester, and carotenoid ester." Additionally, Ultimate Gingko's composition is claimed to (1) provide flavonoid glycosides and terpene lactones to support healthy brain function; (2) provide DHA as a essential fatty acid present in the brain; and (3) provide phosphatidylserine as an important component of brain neurons. *See* Ultimate Gingko, "Fast Facts" at the bottom of the document. Ponroy's composition is "intended to compensate for essential fatty acid deficiencies in the food of delicate of malnutritioned patients." *See, e.g.*, Ponroy, col. 1, lines 7-10. As Ponroy and Ultimate Gingko are directed to different purposes, a skilled artisan would not have been motivated to combine them, let alone substitute the DHA-containing glycerides of Ponroy with DHA in the free fatty acid form from Ultimate Gingko.

Furthermore, the presently claimed compositions "can efficiently increase the LCPUFA-PL level in the body by taking into account the metabolism in the body and without directly using LCPUFA-PL." Paragraph bridging pages 7-8 of the Specification; *see also* Examples 1-6 spanning pages 42-52 of the Specification. As discussed above, neither Ponroy nor Ultimate Gingko teaches this aspect. The presently claimed compositions thus offer unexpected advantages.

In view of the above arguments, 1, 4-5, 8-13, 16, and 21-23 are nonobvious over cited references. Claims 17-18 and 26-30 are canceled, mooting the rejection. Accordingly, Applicants respectfully request withdrawal of the rejection and allowance of the claims.

CONCLUSION

Should the Examiner have any questions or comments regarding Applicants' amendments or response, please contact Applicants' undersigned representative at (202) 230-5119. Furthermore, please direct all correspondence to the below-listed address.

In the event that the Office believes that there are fees outstanding in the above-referenced matter and for purposes of maintaining pendency of the application, or for Notice of Appeal, the Office is authorized to charge the outstanding fees to Deposit Account No. 50-0573. The Office is likewise authorized to credit any overpayment to the same Deposit Account Number.

Respectfully Submitted,

Date: October 4, 2010 By: _____

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PTOL-413A (10-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Applicant Initiated Interview Request Form

Application No.: 10/581,941 First Named Applicant: Hiroshi KAWASHIMA
Examiner: Isaac Shomer Art Unit: 1612 Status of Application: filing RCE

Tentative Participants:
(1) Brian K. Lathrop, Ph.D., Esq. (2) Examiner Isaac Shomer
(3) Zhengyu Feng, Ph.D., Esq. (4) _____

Proposed Date of Interview: _____ **Proposed Time:** _____ **(AM/PM)**

Type of Interview Requested:
(1) [ ] Telephonic (2) [✓] Personal (3) [ ] Video Conference

Exhibit To Be Shown or Demonstrated: [ ] YES [✓] NO
If yes, provide brief description: _____

Issues To Be Discussed

Issues (Rej., Obj., etc)	Claims/ Fig. #s	Prior Art	Discussed	Agreed	Not Agreed
(1)			[ ]	[ ]	[ ]
(2)			[ ]	[ ]	[ ]
(3)			[ ]	[ ]	[ ]
(4)			[ ]	[ ]	[ ]

[ ] Continuation Sheet Attached
[ ] Proposed Amendment or Arguments Attached
Brief Description of Arguments to be Presented:

An interview was conducted on the above-identified application on _____.
NOTE: This form should be completed by applicant and submitted to the examiner in advance of the interview (see MPEP § 713.01).
This application will not be delayed from issue because of applicant's failure to submit a written record of this interview. Therefore, applicant is advised to file a statement of the substance of this interview (37 CFR 1.133(b)) as soon as possible.

Applicant/Applicant's Representative Signature — Examiner/SPE Signature

Zhengyu Feng, Ph.D., Esq.
Typed/Printed Name of Applicant or Representative

66,816
Registration Number, if applicable